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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/602,840	06/23/2000	Julie A. Kirihara	950.011US2	1519

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EXAMINER	
BAUM, STUART F	

ART UNIT	PAPER NUMBER
1638	

DATE MAILED: 09/27/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/602,840	Applicant(s) KIRIHARA ET AL.	
	Examiner Stuart Baum	Art Unit 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 June 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *72,73,78,79,84,86,88-91 and 94-110* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *72-73, 78-79, 84, 86, 88-91, 94-110* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

1. The amendment filed June 19, 2002 has been entered.

Claims 72, 73, 78, 79, 97, and 98 have been amended.

It was noted in Appendix A that claim 94 was to be canceled, but this request was not entered. All changes to the claims and specification must be first addressed in the body of the amendment. Applicants will have to submit a new amendment to cancel claim 94.

Claims 72, 73, 78, 79, 84, 86, 88-91, and 94-110 are pending and will be examined.

2. The text of those sections of Title 35, U.S. Code not included in this office action can be found in a prior office action.

3. The rejection of claims 72, 73, 78, 79, 84, 86, 88-91 and 94-110 under 35, U.S.C. 112 first paragraph for lack of written description, is withdrawn based on Applicant's amendments and arguments.

4. Claims 72-73, 78-79, 84, 86, 88-91, and 94-110 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This rejection is maintained for the reasons of record set forth in the Official action mailed 2/13/02. Applicant's arguments have been fully considered but they are not persuasive.

Applicant contends that it would not be undue experimentation to readily produce many lines expressing 19 kD and 22 kD α-zein plant seed storage proteins. Applicant continues by

stating "the fact that three of eight samples exhibited a statistical increase in lysine demonstrates the repeatability and enablement of the technique" (page 8, last sentence, first paragraph). Applicant believes that the teachings of Coleman et al (1997) further support their contention of enablement because the mutants *opaque2* and *floury2* are reported to produce "soft, starchy endosperms" because of aberrant expression of α-zeins. Lastly, Applicants review the findings of Marks et al (1985) that there is a strong structural relation among zeins and that there is no basis for the Examiner's contention that different isoforms have "divergent functions" (page 9, 1st full paragraph).

The Examiner contends that the specification does not reduce to practice the purported invention of the Applicants. The specification only teaches one skilled in the art how to make maize seeds comprising decreased amounts of the amino acid leucine while increasing the amount of the amino acid lysine. The specification does not teach how to make a fertile transgenic *Zea mays* plant having an increased starch content comprising transforming a 19 kD or 22 kD α-zein plant seed storage protein into said plant. The specification also does not teach how to evaluate or assay a plant for possessing an increased amount of starch in the seeds. Applicant does not address the issue of enablement, rather Applicant only addresses the validity or applicability of references cited by the Examiner in support of undue experimentation to make and/or use the claimed invention. For example, the Applicant contends enablement for transforming plants to achieve the claimed invention but only addresses an increase in lysine (page 8, lines 2-3). Applicant also contends that Coleman et al demonstrates the enablement of Applicants' claims (page 8, 2nd paragraph) but Coleman et al do not teach making increased starch, they only describe seeds with a "soft, starchy endosperm" (page 7094, left column, 2nd

paragraph) and no mention is made about increasing the starch content of the seeds. Furthermore, while Applicants claim maize seeds with increased starch content, the specification does not mention increased starch content or methods for evaluating the starch content of maize seeds.

5. The rejection of claims 78, 79, 101 and 102 under 35, U.S.C. 101 is withdrawn based on Applicant's amendments and arguments.

6. Claims 88-89, 90-91, and 102-107 and all subsequent dependent claims are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This rejection is maintained for the reasons of record set forth in the Official action mailed 2/13/02. Applicant's arguments have been fully considered but they are not persuasive.

Applicant contends that the terms "substantially complementary" and substantially identical" are defined in the specification at page 12, lines 11-24 and that "one of ordinary skill in the art would understand what is claimed when the claims are read in light of the specification" (page 11, end of first paragraph).

The Examiner does not agree that the dispositive evidence as presented by the Applicant, that said terms are definite. First of all, the specification states (page 12, line 13) that "substantially identical" means that two nucleic acid or amino acid sequences have at least about 65% sequence identity. Second, Marks et al (1985) teach that the cDNA clones from maize that are homologous to the 22 kD α-zein polypeptides exhibit 92% sequence identity, and the cDNA

clones from maize that are homologous to the 19 kD α-zein polypeptides exhibit 75-95% sequence identity. And hence, sequences that are 65% homologous to either the 22 or 19 kD α-zein storage proteins are not themselves α-zein storage proteins and would have a different structure and function. Therefore, the specification does not make clear or definite the meaning of "substantially identical" or "substantially complementary" and as such the terms are still deemed indefinite.

7. No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stuart Baum whose telephone number is (703) 305-6997. The examiner can normally be reached on Monday-Friday 8:30AM – 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (703) 306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 or (703) 305-3014 for regular communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the legal analyst, Sonya Williams, whose telephone number is (703) 305-2272.

Stuart Baum Ph.D.

September 19, 2002